

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Status of the Claims

Claims 1, 6, and 13 are amended to correct typographical errors. Claims 1 and 2 are amended to point out the claimed invention more clearly, as detailed below. Claim 15 is amended to eliminate an erroneous designation of “/min.” These changes are made without prejudice or disclaimer, and applicants reserve the right to pursue any canceled subject matter in one or more applications with the same rights of priority as the present application. Upon entry of these amendments, claims 1-15 will be pending.

II. Rejections Under 35 U.S.C. § 112

The examiner rejects claims 1-15 under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness. In particular, the examiner asserts that the term “linear flow” rate is a relative term and depends upon the place of measurement in the chromatographic system. Applicants have revised the claims to indicate that the measurement is taken during loading of the bio-molecule-containing fluid to the chromatographic column. Support can be found, for example, at [0061] of US 2007/0092960. Since the changes obviate the rejection, its withdrawal is requested.

III. Rejections Under 35 U.S.C. § 102

The examiner rejects claims 1, 5-10, and 12-15 for alleged anticipation by Kawakami *et al.*, as evidenced by Hirai *et al.*, Mitoma *et al.* and Yashida *et al.* Applicants respectfully traverse the rejection.

The invention is directed to an industrial-scale method of fractionating and/or isolating bio-molecules from fluids. *See, e.g.* US 2007/0092960, [0001]. In particular, the claimed methods involve the use of high temperature and high flow rate. *Id.* Regarding the later, the specification makes clear that unlike conventional flow rates of about 200 cm/hr, the

inventive methods employ high flow rates of from about 1500 to 12000 cm/hr with rates typically being about 3000 to 7000 cm/hr. *Id.* at [0061].

Some of the flow rates cited in the specification and claims recite a period (.) instead of a comma (,). Nevertheless, an artisan reviewing the specification would recognize that the periods as typographical errors. As noted above, for instance, the specification makes clear that the inventive processes use flow rates higher than 200 cm/hr. *Id.* In addition, flow rates referenced in examples 3-6 and 10-13 do not contain the aberrant periods. Accordingly, one of ordinary skill in the art would recognize that the term "1,500 cm/hr" denotes 1500 c/m hr or 1,500 cm/hr and not 1.5 cm/hr. To remove any potential ambiguity, applicants have replaced with commas those flow rates in the specification and claims containing periods.

As to the cited art, Kawakami is invoked for its alleged teaching of a process for isolating lactoferrin using a chromatographic column with a flow rate of 3.1 cm/min (i.e., 186 cm/hr) and a process temperature of 50°C. As noted above, the claimed processes involve the use of high flow rates, i.e., rates of at least 1500 cm/hr. Kawakami fails to teach an isolation process with such a flow rate. Accordingly, Kawakami cannot anticipate the pending claims, and applicants respectfully request withdrawal of the rejection.

IV. Rejections Under 35 U.S.C. § 103

The examiner rejects claims 1-15 over Kawakami *et al.* as evidenced by Hirai *et al.*, Mitoma *et al.* and Yoshida *et al.* Applicants respectfully traverse the rejection.

Kawakami's disclosure is discussed above. Hirai is cited for teaching that Cellulosine has a particle diameter of 45 to 105 um, and Mitoma is cited for teaching that lactoferrin has a molecular weight of 80,000 Daltons. Meanwhile, the examiner cites Yoshida for allegedly disclosing the size and density of Chitopearl particles. None of the secondary references cures the deficiencies of Kawakami, however. Thus, no combination of the cited material yields the claimed processes. Since the examiner thus has not established a *prima facie* case of obviousness, applicants request withdrawal of the rejections.

Applicants further submit that the application is in condition for allowance. An early indication to this effect is requested. Examiner Kim is invited to contact the undersigned directly, should he feel that any issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, then applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

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